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## **The Norwegian National Council for Priority Setting in Health Care: Decisions and Justifications<sup>1</sup>**

**Abstract:** Different countries have adopted different strategies for tackling the challenge of allocating scarce health care resources fairly. Norway is one the countries that has pioneered the effort to resolve priority setting by using a core set of priority-setting criteria. While the criteria themselves have been subject to extensive debate and numerous revisions, the question of how the criteria have been applied in practice has received less attention. In this paper, we examine how the criteria feature in the decisions and justifications of the Norwegian National Council for Priority Setting in Health Care, which has played an active role in deliberating about health care provision and coverage in Norway. We conducted a comprehensive document analysis, looking at the Council's decisions about health care allocation as well as the reasons they had provided to justify their decisions. We found that although the Council often made use of the official priority-setting criteria, they did so in an unsystematic and inconsistent manner.

### **1. Introduction<sup>2</sup>**

Priority setting in health care is a necessary, but difficult and complex task that can be tackled in different ways. Some countries have chosen to address this challenge by adopting a set of principles or criteria that are to be applied to a wide range of priority-setting decisions, often reflecting broader public debates about what values are relevant for rationing (see e.g. Berg and van der Grinten, 2003; Calltorp, 1999; Landwehr and Klinnert, 2015; Rumbold et al,

forthcoming). Norway is one of the countries that has spearheaded this approach. Concerted efforts have been made from an early stage to take a systematic approach to priority setting, and through the work of several national commissions, a set of three official priority-setting criteria has been developed, in principle applicable to all kinds of priority-setting decisions (Kapuriri et al, 2007; Norheim, 2003) (Table 1).

(Table 1 about here)

While the criteria themselves have been subject to extensive public debate and several revisions – most recently in the work of the third Priority Commission and its critics (Directorate of Health, 2015; NOU, 2014)<sup>3</sup> – questions concerning how the criteria are being applied in concrete priority-setting decisions have received less attention. The criteria were intended as overarching criteria for priority-setting at all levels of the health care services (Directorate of Health, 2012; NOU 1997), and thus it is an important question how and to what extent they are being used in practice. In Norway, the National Council for Priority Setting in Health Care (‘the Council’) is one of several institutions involved in macro-level priority setting in the health care services.<sup>4</sup> In this paper, we look at how the Council has applied the official priority-setting criteria in deliberating and making decisions about the allocation of health care resources. We were interested in firstly, how the criteria were in fact being used by the Council, and secondly, whether the Council’s use of the priority-setting criteria could shed light on how priority setting happens in practice. For this purpose, we examine how the three criteria feature in the Council’s decisions<sup>5</sup> and justifications. By means of a comprehensive document analysis of all cases processed by the Council from 2007 to 2014, we examined first, what decisions the Council had made, and second, what reasons they

had provided to justify their decisions. In particular, how were the three criteria reflected in the justifications they gave, and what other reasons, if any, were offered?

The work of the Council is of interest for a number of reasons. The Council has been active since 2007 - and its predecessor since 2002 – but its work is not well known in the international debate, in contrast to the work of e.g. NICE (see e.g. Culyer, 2006; Devlin and Parker, 2004; Rumbold et al, forthcoming). Within Norway, naturally, the work of the Council has received much more attention (e.g. Agenda Kaupang, 2015; Johansson et al, 2009; NOU, 2014; Ringard et al, 2010; Ringard, Mørland and Larsen, 2012; Ringard, Larsen and Norheim, 2012; Wang and Høymork, 2014). However, to date, no systematic analysis has been conducted of the Council's justifications for their decisions, and our paper makes a novel contribution in this respect. Furthermore, the Council has made substantial efforts to promote transparency in their work. Their recommendations and justifications, as well as all case documents and summaries of their deliberations, have been made freely accessible to the public via the Council website, and all Council meetings are open for the public to attend. This offers a rare opportunity to gain some insight into how they make their decisions.

## **2. The Norwegian National Council for Priority Setting in Health Care**

The Council was established in 2007 by the Norwegian Ministry of Health and Care Services, following the recommendations of the second Priority Commission (NOU, 1997). The

Council replaced the earlier National Priority Council, which was active from 2002 to 2006 (Mørland et al, 2010). In the period from 2007 to 2014, the Council had 25 members, representing national and regional health management and administration, the health care professions, user and patient organizations and academia. The broad composition of the Council is intended to ensure that all important stakeholders and perspectives are represented. In addition, the Council has four ex officio members constituting its Secretariat, hosted by the Norwegian Knowledge Centre for the Health Services (until 2016).

The Council was intended as an arena for discussing governance and development in quality improvement and priority setting in the health services at a national level. Its mandate is to help ensure a comprehensive and consistent approach to quality improvement and priority setting, by clarifying the roles and responsibilities of different actors in the health care sector and improving coordination and interaction between the different levels, such as the primary care and specialist services (Mørland et al, 2010; Ringard, Mørland and Larsen, 2012; National Health Plan (2007-2010)).<sup>6</sup> It is also part of the Council's mandate to promote public debate on the specific cases it deals with as well as on priority setting in health care in general (the Council website).

The Council's primary role is to deliver assessments and recommendations concerning priority setting (and up until 2015, quality improvement) in the health care services to health management and authorities, policy makers and governing bodies (the Council website; Mørland et al, 2010; Ringard, Mørland and Larsen, 2012). These recommendations, however, are not binding, but merely advisory.

(Table 2 about here)

### **3. Materials and methods**

Our analysis covers the Council's activity between 2007 and 2014. We reviewed all cases processed within this period.

#### *Materials*

We reviewed the following documents, all available via the Council's website:

- Case documents: case vignettes, case presentation documents, and all supporting documents on which the vignette and presentation documents were based
- Presentations at meetings (available as PowerPoint or PDF files)
- Meeting minutes, summarising the Council's discussion
- Final decisions: The Council's final assessment, as communicated directly to the public on their website, which includes their recommendations and justifications.

#### *Case selection*

The Council website details a number of activities in addition to its recommendations in particular priority-setting cases. Such additional content includes, for example, information about past and upcoming public meetings and conferences as well as other events related to priority setting in the Norwegian health care services. We were only concerned with the Council's actual decisions – thus, it was necessary, first, to identify the subset of cases where the Council had issued a recommendation on specific priority-setting questions. Subsequently

we completed a thorough review of the selected cases, acquiring detailed knowledge of each case and identifying the Council's justifications for their recommendations. Both authors reviewed the cases independently, and subsequently we compared and discussed our findings. As discussed in further detail below, it was not always straightforward to identify the basis for the conclusion, or the conclusion itself. The independent review of the cases was helpful, as was the comparison and discussion of the lists each of us came up with. We were able to reach an agreement for each of the cases, but due to the nature of the documents and the ambiguity of some of the cases, we cannot guarantee that a third reviewer would have made the same assessment in all of the cases.

First, each reviewer identified all cases that concerned coverage of new and existing health care treatments and interventions. . Second, we narrowed down this larger set of cases to cases where the Council's final decision contained one or more concrete advisory statements regarding coverage of the treatment or intervention in question. For any given case, the Council had often issued a range of recommendations, including recommendations for further research and quality improvement, but we restricted our analysis to those recommendations that specifically concerned coverage. The Council's engagement with a case tended to be fairly broad; thus, it was often not immediately clear whether the Council had set out to address specific questions or what these were. Although the case vignette would typically highlight key questions for consideration, the Council's recommendations did not always correspond to these questions. The 'central questions' listed in Table 3 have been defined by 'post hoc' reconstruction based on the case vignettes, the meeting minutes and the final decisions. Recommendations are put forward as part of the Council's 'final decision', a more general assessment that sums up key issues and often covers a variety of aspects of the case.

However, the recommendations themselves are not always clearly indicated within this broader piece of text. Thus, for some of the cases, identifying recommendations required some level of interpretation.

#### *Analysis of the Council's decisions and justifications*

Subsequent to the selection of those cases in which the Council had issued one or more concrete recommendations, we sought to identify the reasons the Council had provided in support of their recommendation. Justifications, like the recommendations, are also to be found in the body of text that constitutes the Council's final decision. Justifications tended not to be stated explicitly or spelled out in detail, and it was not always obvious whether a given consideration was specifically intended as a justificatory reason for the recommendation that was issued, or whether it was instead included merely as a general observation. Thus, there was a certain level of ambiguity with regards to what was intended by the Council as justificatory reasons. Some interpretation, therefore, was required for identifying the Council's justifications.

We were primarily interested in the Council's use of the official priority-setting criteria in their justifications, but also registered the use of other supporting reasons. The Council's references to the three priority-setting criteria varied somewhat with respect to how direct or explicit they were, and we distinguish between 'direct' and 'indirect' references to each of the criteria. 'Direct' references include all explicit mentioning of a criterion, as well as quite specific references to the content of the criterion, but without specifically naming the criterion itself. For example, we considered a statement such as 'The costs are high, but not sufficiently so to count against inclusion of the vaccine' (*HPV vaccine*) as a reference to the cost-



effectiveness criterion, even if it is not specifically stated that the cost-effectiveness criterion is met. Similarly, we considered statements about poor prognosis and high morbidity and mortality (*Left ventricular assist device*) as direct references to the severity criterion. Statements about the level or quality of evidence of effectiveness were considered direct references to the expected benefit criterion. In three of the cases, the Council made reference to factors that would impact on whether the Expected benefit criterion is met, even if that factor is not directly contained in the criterion itself. For example, the possibility of false positives was offered as a justifying reason in *Genetic testing*, and risk of complications was mentioned in both *Screening for colorectal cancer* and *Surgical treatment of obesity*. We included these justifying reasons as ‘indirect’ references to the Expected benefit criterion. Finally, reasons offered in support of the Council’s decisions with no clear relation to the official priority-setting criteria were recorded as ‘other’ reasons. We included references to the WHO criteria for screening in this category. These criteria – ten in total – include significance of the health problem, availability of effective treatment and costs (Wilson and Jungner 1968), and as such one could say that there is some overlap between the WHO criteria and the official priority-setting criteria. However, as the Council did not specify which of the ten WHO criteria they had in mind, we counted their references to the WHO criteria as a reference to ‘other’ justifications.

For each case, we also considered whether the Council’s decision and justification complied with the official priority-setting criteria. Here, we conducted an in depth analysis of the background information for the case and the Council’s deliberations as per the meeting minutes. Thus we aimed to determine first, to what extent the Council had taken a position on

whether each of the three criteria had been met, and second, whether their final decision was in accordance with that position.

Finally, we considered whether there were any trends across time with respect to the Council's use of the criteria.

## 4. Results

### *Cases*

We identified 18<sup>7</sup> cases that met our selection criteria, out of a total of 105 cases processed between 2007 and 2014. The selected cases with decisions and justifications are presented in table 3.

(Table 3 about here)

The number of cases with one or more clearly identifiable and concrete advisory statements on health care coverage was fairly low. As described above, many of the Council's cases concerned quality improvement or were merely intended for general discussion. Nevertheless, it is noteworthy that we had to exclude several cases from our analysis because the recommendation was too general or vague, or because it was simply unclear whether a recommendation had been made.

### *The Council's use of the official priority-setting criteria*

The Council had provided a justification for their recommendation in 15 of the 18 cases – the remaining three cases lacked a justification. The Council made reference to the official priority-setting criteria in their justification in 12 of these cases (the Council's use of the criteria is summarised in table 4). However, the Council generally only referred to one or two of the criteria, rather than using all of the criteria together. Furthermore, in some of the cases where the Council had made reference to a criterion in their justification, it was not clear whether they thought the criterion had been met. The Expected benefit criterion was used the most, appearing in eight cases, while the Cost-effectiveness criterion was used in seven cases. The Severity criterion was used the least, cited in only five cases. We did not detect any pattern in the Council's use of the criteria over time.

(Table 4 here)

Insofar as the Council had referred to each of the three official priority-setting criteria, their recommendations were usually in accordance with the criteria. Two recommendations were justified on the grounds that two of the criteria had been met (*Smoking cessation, HPV vaccine*). Conversely, several recommendations against the inclusion of a treatment or intervention were justified on the grounds that one or more of the criteria had either not been met (*Cochlear implants, Rotavirus vaccine, Screening for postnatal depression*), or that there was insufficient documentation thereof (*Heart valves, Left ventricular assist device (2008), Genetic testing*).

However, there were some noteworthy exceptions to this general pattern. In the first cluster of exceptions, the Council made recommendations that were arguably in conflict with their own

judgment concerning one or more of the three criteria, with no clear explanation or justification offered for the departure from the criteria. In *Early ultrasound*, the Council's preliminary decision indicated that there were no grounds for expecting early ultrasound to yield any medical benefits for either the mother or the foetus – it seems, then, that they took the view that the Expected benefit criterion had not been met. Nevertheless, in their final decision, the Council made a recommendation in favour of the introduction of early ultrasound screening. The preliminary decision and the discussion indicate that the Council believed that other concerns beyond the official priority-setting criteria – in particular, early diagnosis of Down's syndrome, as well as social inequalities in access to services – might be relevant for evaluating the introduction of early ultrasound. But this is not made explicit, nor is there any record of a discussion of whether such other concerns are sufficiently weighty to justify an exception to the official priority-setting criteria. . In *Climate therapy abroad*, the Council recommended that the scheme should be continued. However, their discussion of the case indicates that there was great uncertainty concerning both effectiveness and cost-effectiveness. Yet, no explicit justification was provided for continuing the scheme in spite of such uncertainty, beyond an emphasis on the need for further research to assess the effects and the costs of this treatment.

In the second cluster of exceptions, the Council's decision was mixed, allowing for exceptions to their general recommendation subject to individual assessment by health care professionals. However, they did not offer any reasons for why such exceptions should be allowed, even though the exceptions seemed to violate one or more of the official priority-setting criteria. In *Long-term mechanical ventilation*, the Council states explicitly that this intervention 'does not meet the priority-setting criteria'. It was clear from the Council's

discussion that they considered the costs to be well above any reasonable cost-effectiveness threshold. (The discussion suggests that they also had severe doubts about whether the expected benefit criterion had been met, but it is unclear what position they took on this point in the end). Similarly, in *Cochlear implants*, the high costs relative to the expected benefit was the stated reason for not granting a right to a second implant. In both cases, it is unclear on what grounds they recommended that the intervention should nevertheless be available to selected patients. The *Surgical treatment of obesity* case also bore some resemblance to these two cases, in that there seemed to be some incongruence between one part of the recommendation and the considerations they raise in relation to the expected benefit criterion. The Council recommended prioritizing non-surgical interventions, apparently on the basis of uncertainty concerning the long term effects and the high risks of side effects of surgery, but nevertheless they also recommended against restricting eligibility for such surgery. No further reasons were given to explain the basis for this latter part of their decision.

The Council sometimes made reference to other kinds of considerations in their final decision. These included: international guidelines; the lack of an alternative intervention or treatment; fear in the population; the importance of preventive interventions; reduce social inequalities in health; total budgetary implications; treatment already in use; public trust in the health care services; the WHO screening criteria. Often, where such other considerations had been emphasised, they were offered as further but secondary support for a recommendation based on one or more of the official priority-setting criteria, though there were some exceptions. In *Breast reconstruction surgery*, *Left ventricular assist device* and *Monoclonal antibodies*, the appeal to other considerations appear to have been made in order to support a recommendation where the recommendation's compliance with the official priority-setting

criteria was not clear-cut, though this was not made explicit. In *Breast reconstruction surgery*, the Council made a recommendation that, effectively, gave higher priority to this intervention than under the status quo.<sup>8</sup> However, the rationale for this decision was unclear. The Council noted that the costs are very high and that the evidence base for expected benefit and costs should be strengthened, but it is not clear from their discussion or final decision what conclusion they reached with respect to either expected benefit or cost-effectiveness. Although they referred to ‘international guidelines’ as an alternative justification, they did not explain why this particular consideration should be given weight in this instance. In the reconsideration of the *Left ventricular assist device* case in 2013, the Council concluded that the intervention should be offered to carefully selected patients, in light of somewhat better evidence of clinical effectiveness. The Council acknowledged that the costs of the intervention were high and that cost-effectiveness was low, but it also pointed out that eligibility for the treatment was likely to be limited to only eight to twelve patients per year. Although this observation is not explicitly offered as a justificatory reason, it is possible to read the statement as a claim about low overall costs or budgetary implications, which may have been intended as a reason justifying ‘overriding’ the cost-effectiveness criterion. In *Monoclonal antibodies*, the Council gave a ‘conditional approval’ of the treatment, recommending that it be made available to patients within a clinical phase IV study. Their main concern was the high costs of these drugs, and this appears to have been the reason for their recommendation against the inclusion of these drugs in the standard treatment protocol. Two reasons are offered that, like in the *Left ventricular assist device* case, can be read as reasons that justify overriding the cost-effectiveness criterion: Firstly, the drugs were already in use, and secondly, availability of the drug via a clinical phase IV study would not entail an increase in general health expenditures.

## 5. Discussion

The Council issued concrete recommendations in a fairly low number of cases. The tendency to issue advisory statements of a more general nature was also noted by the Kaupang report and the third national Priority Commission in their evaluations of the Council's work (Agenda Kaupang, 2015; NOU, 2014). Both reports emphasised the need for more specific and concrete advice. The Kaupang report suggested that the Council's consensus based approach might partly explain this feature of the Council's recommendations, which seems plausible: the more specific and concrete the recommendation, the more scope for disagreement. In particular, this seems likely given the Council's broad composition, with members representing different stakeholders in health care and a diverse and sometimes conflicting set of interests and perspectives. In this context, where it may be difficult to reach an agreement, a consensus based approach may serve as a disincentive to issuing more concrete recommendations. Recommendations that in a sense deferred part of the decision-making to other parties can also be seen in this light: allowing some level of flexibility in the decision, as opposed to being absolute – e.g. by giving a mixed recommendation or allowing for individual exceptions – might also increase the likelihood of obtaining a consensus. Alternatively, a concern to preserve some degree of local autonomy may also have motivated less absolute decisions.

While the Council often appealed to the official priority-setting criteria to justify their recommendations, they did not do so in a systematic or consistent manner.. Firstly, in six out of 18 cases, the Council made no explicit reference to any of the official priority-setting criteria in their final decision. Secondly, the Council did not use all three criteria together, but referred to only one or two at a time, without explaining why they employed some of the criteria but not others. Importantly, the three criteria should have been used together, according to the recommendations of the second Priority Commission (NOU 1997) and the relevant legislation in effect at the time. In some of the cases, the failure to refer to one or more of the criteria seemed to have been ‘innocent’, in the sense that whether or not the omitted criterion had been met was considered self-evident or uncontroversial, and compliance with it thus implicitly assumed. In particular, this often seems to have been the case for the Severity criterion (e.g. *Genetic testing*, *Heart valves*) – we can reasonably expect to find more discussion of this criterion in cases where a condition’s level of severity was not clear-cut. In other cases, however, it was simply not clear why some of the criteria had not been cited, nor was it always possible to deduce from the Council’s deliberation what their stance was with regards to the criteria that were not mentioned in their final decision. Thirdly, there were also several cases where recommendations and justifications were mixed in terms of their compliance with the criteria, without the Council giving explicit reasons for their departure from the criteria. There are reasons to be concerned about the lack of a systematic and principled approach to the use of the criteria

We suggest that two sets of factors may help explain the unsystematic, and to some extent inconsistent use of the criteria in the Council’s decisions and justifications. Firstly, the criteria themselves may not always provide adequate support for decision-making. Secondly, certain



features of the Council may influence their decision-making process and its outcomes. We consider each in more detail below.

The official priority-setting criteria have been widely endorsed and have been attempted implemented in the health care services in various ways. At the same time, however, it has been pointed out that the criteria have been difficult to apply in practice (NOU, 2014; Wisløff, 2015). One important concern in that respect is the discretionary nature of the official priority-setting criteria, which arguably imposes some limitations on the level of decision support that they provide. Neither of the criteria has been formulated in very precise or concrete terms, and thus require significant discretionary judgement: ‘Not insignificant’, ‘expected to benefit’ and ‘reasonable ratio of costs to benefits’ are all statements with considerable interpretative space. In particular, the severity criterion allows for a wide range of possible interpretations (see Robberstad 2015). Thus, in some cases it may be difficult to reach an agreement on whether the criteria have been met; accordingly, an advisor or decision-maker might be hesitant to attribute much weight to this consideration in reaching a decision. Conversely, however, a criterion that is formulated in less precise terms may be marshalled ad hoc to support a wide range of decisions. A further issue is how the criteria should be weighed against each other in cases where they conflict. To a large extent, this question was left open by the second Priority Commission – their discussion highlights important challenges but is not conclusive, and they allowed that different weights may be assigned to the criteria depending on the objective of the evaluation (NOU 1997).<sup>9</sup>

To some extent, the Council’s deliberations reflect some level of difficulty in applying the criteria. First, in the *Breast reconstruction surgery* case, the question of how the severity

criterion should be interpreted in relation to this group of patients came up in the discussion – more specifically, how much weight should be attributed to concerns about quality of life in the evaluation. Second, the *Climate therapy abroad* case featured a discussion of the application of the expected benefit criterion, and of whether the benefits of the intervention were sufficient to meet the criterion. It is not clear from the discussion what, if any, conclusions were reached in each case, and the Council made no reference to these criteria in the final decision. At the same time, however, potential difficulties in applying the criteria does not explain why, in some cases, the Council did not consider the criteria at all.

The second set of factors concerns certain features of the Council itself. One important consideration is the formal status of the Council. The Council's role is primarily advisory, and the health authorities and other governing bodies are under no obligation to abide by the Council's recommendations. Thus, it is somewhat unclear how one might characterise the status and implications of the Council's final decisions. We suggest that this lack of formal decision power may be part of the explanation for the Council's lack of a systematic and principled approach to arriving at, and justifying, their decisions. The need for accountability, through for example clear and detailed explanations of the rationale behind decisions, may seem less pressing when the decisions are 'merely' advisory, and the responsibility for making a decision lies elsewhere. A further concern is the composition of the Council and its internal dynamic. As we have already remarked upon, the members of the Council are selected to represent different stakeholders in health care, with diverse and sometimes conflicting sets of interests. On the one hand, this approach ensures that a range of perspectives will be represented and may be an effective means to promote debate, which is part of the Council's mandate. But on the other hand, insofar as members are prone to act as

advocates of their stakeholder group's interests, conflicting interests will likely make reaching an agreement more difficult.<sup>10</sup> Furthermore, as Landwehr and Klinnert (2015) have suggested, different parties – e.g. health economists versus patient representatives – may represent different values, which in turn will likely affect how much weight they attribute to considerations such as cost-effectiveness.

It is beyond the scope of this paper to consider in further detail the extent to which different kinds of institutional properties and practices may promote or hinder good decision-making. Here, we merely wish to point to the possibility that such factors play a role in how an institution like the Council makes its decisions, and to suggest that this question merits further discussion and research.

Lastly, we offer a few observations regarding our finding that the Council referred to a wide range of considerations other than the official priority-setting criteria in support of their recommendations (see also Wang and Høymork (2014) on this point).

It is notable the Council was not explicit about what role these other considerations played in their deliberation. Furthermore, they did not provide any details about their procedure for deciding when and why other considerations were relevant. Finally, no details were given about how these other considerations were weighed relative to the official priority-setting criteria in reaching a decision. Clearly, further discussion is needed about the appropriate procedure for identifying and incorporating other morally relevant concerns.

## **6. Conclusion**

In this paper, we examined the Priority Council's coverage decisions and the reasons they provided to justify these decisions, with a particular focus on the extent to which their justifications reflected the official priority-setting criteria. While for the most part, the criteria seemed to have played an important role in the Council's decisions and justifications, it was also evident that they did not always apply the criteria in a systematic and principled manner.

We suggested that these findings may in part be explained by a combination of factors, including the discretionary nature of the three criteria, the Council's lack of formal decision-making power, as well as the compositions of its members and their dynamic. In particular, the latter two point towards a more general lesson. The international academic debate on priority setting in health care tends to focus either on what criteria, principles or values should inform our decisions, or on defining fair decision-making procedures. Our study of the Norwegian National Council suggests that we ought to pay more attention to the appointed institutions that are tasked with making priority-setting decisions. Whether such institutions rely on substantive criteria or fair procedures, their role, design and structure may influence the decisions that are being made. The question of how priority-setting institutions should be designed in order to foster good decision-making deserves a more prominent place in the debate on the fair allocation of health care resources.

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<sup>1</sup> Author 1 has no prior or current engagement with the Council. Author 2 was previously in the Secretariat of the first Priority Council, from 2002 to 2006.

<sup>2</sup> Acknowledgements withheld to preserve anonymity.

<sup>3</sup> For a commentary on these revisions, see Bringedal (2015).

<sup>4</sup> Designated priority-setting institutions and agencies can also be found in other countries, e.g. Canada (the Canadian Agency for Drugs and Technologies in Health), Germany (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen and Gemeinsamer Bundesausschuss), France (Haute Autorité de Santé), the UK (the National Institute for Health and Care Excellence) and Sweden (Prioriteringscentrum). The role that such bodies play and their level of responsibility vary.

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<sup>5</sup> The Council's decisions are perhaps more accurately characterised as recommendations and assessments, as their recommendations are not binding, and the final decision-making authority lies with policy makers and governing bodies. Nevertheless, for the sake of simplicity, we will refer to the Council's issued statements as 'decisions'.

<sup>6</sup> In the course of the Council's existence it has undergone several changes to its mandate. One of the more substantial changes is the narrowing of the mandate from dealing with issues concerning both quality and priority setting in the health services to focusing only on the latter. This change was implemented in 2015 and thus does not affect our analysis, which covers the work of the Council in the period from 2007 to 2014.

<sup>7</sup> One of the cases, Left Ventricular Assist Device, was handled twice, in 2008 and in 2013, when the Council revised their earlier position. We count this as one case, but consider the different justifications they provided separately.

<sup>8</sup> The implication of including reconstructive surgery in the treatment plan for breast cancer is that patients will have a right to an assessment for such surgery in accordance with the Patient Rights Act, which in practical terms means that the patient will be seen sooner.

<sup>9</sup> Because of these and related issues regarding the application of the criteria, reviewing the criteria was a central task for the third Priority Commission. Their recommended revisions to the criteria sought to address these concerns (NOU, 2014).

<sup>10</sup> In fact, that this kind of dynamic was often an issue in the Council's discussions was suggested to us by one previous member of the Council (Bjarne Robberstad, in conversation). Unfortunately, this very interesting issue lies beyond the scope of what our document analysis can address.

## References

Agenda Kaupang (2015), *Evaluering av Nasjonalt råd for kvalitet og prioritering i helse- og omsorgstjenesten* [Evaluating the National Council for Quality and Priority Setting in Health Care], Ministry of Health and Care Services, Report no. 8746.

Berg, M. and T. van der Grinten (2003), 'The Netherlands', in: C. Ham and R. Glenn (Eds), *Reasonable Rationing: International Experience of Priority Setting in Health Care*. Maidenhead, UK: Open University Press.

Bringedal, B. (2015), 'Verdensmester i teoretisk prioritering' [World champions in theoretical priority setting], *Nytt Norsk Tidsskrift*, 1.

---

Calltorp, J. (1999), 'Priority setting in health policy in Sweden and a comparison with Norway', *Health Policy*, 50 (1-2): 1-22.

Culyer, A. J. (2006), 'NICE's use of cost effectiveness as an exemplar of a deliberative process', *Journal of Health Economics, Policy and Law*, 1: 299-318.

Devlin, N. and D. Parker (2004), 'Does NICE have a cost-effectiveness threshold and what other factors influence its decisions? A binary choice analysis', *Health Economics*, 13: 437-452.

Directorate of Health (2012), *Prioriteringer i Helsesektoren: Verdigrunnlag, Status og Utfordringer* [Priority setting in the health sector: Core values, status and challenges], Norwegian Directorate of Health.

Directorate of Health (2015), *På ramme alvor: Alvorlighet og prioritering* [Severity and priority], Norwegian Directorate of Health.

Johansson, K. A., I. Miljeteig and O. F. Norheim (2009), 'Høykostnadsmedisin – mangler vi åpne og legitime prosedyrer for prioritering?' [High cost drugs – do we lack open and transparent procedures for priority setting?] *Journal of the Norwegian Medical Association*, 129: 17–20.

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Kapiriri, L., O. F. Norheim and D. K. Martin (2007), 'Priority setting at the micro-, meso- and macro-levels in Canada, Norway and Uganda', *Health Policy*, 82 (1): 78-94.

Landwehr, C. and D. Klennert (2015), 'Value congruence in health care priority setting: social values, institutions and decisions in three countries', *Health Economics, Policy and Law*, 10: 113-132.

Mørland, B. (2009), 'The history of health technology assessment in Norway', *International Journal of Technological Assessment in Health Care*, 25: 148-155.

Mørland, B., Å. Ringard and J-A. Røttingen (2010), 'Supporting tough decisions in Norway: A healthcare system approach', *International Journal of Technology Assessment in Health Care*, 26: 298-404.

Nasjonal helseplan [National Health Plan] (2007-2010).

<https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/sykehus-i-norge/id115230/>

[Last accessed on December 15, 2015]

Norheim, O. F. (2003), 'Norway', in C. Ham C and G. Robert G (Eds), *Reasonable Rationing*. Philadelphia: Open University Press.

---

NOU (2014), *Åpent og rettferdig – prioriteringer i helsetjenesten* [Open and fair – priority setting in the health care services], NOU 2014: 12, Oslo.

[www.regjeringen.no/no/dokumenter/NOU-2014-12/id2076730/](http://www.regjeringen.no/no/dokumenter/NOU-2014-12/id2076730/)

[Last accessed on December 15, 2015]

NOU (1997), *Prioritering på ny – Gjennomgang av retningslinjer for prioriteringer innen norsk helsetjeneste* [Priority setting revisited – review of guidelines for priority setting in the Norwegian health care services], NOU 1997: 18, Oslo.

[www.regjeringen.no/nb/dep/hod/dok/nouer/1997/nou-1997-18/4.html?id=140960](http://www.regjeringen.no/nb/dep/hod/dok/nouer/1997/nou-1997-18/4.html?id=140960)

[Last accessed on December 15, 2015]

Patient Rights Act LOV-1999-07-02-63 [www.lovdata.no/all/hl-19990702-063.html](http://www.lovdata.no/all/hl-19990702-063.html)

[Last accessed on August 10, 2015]

Patient Rights Act LOV-2015-05-22-32. [www.lovdata.no/all/hl-19990702-063.html](http://www.lovdata.no/all/hl-19990702-063.html)

[Last accessed on December 15, 2015]

Regulation on Medicines: FOR-2010-06-23-957

<https://lovdata.no/dokument/SF/forskrift/2009-12-18-1839>

[Last accessed on December 15, 2015]

Regulation on Priority Setting FOR-2000-12-01-1208

<https://lovdata.no/dokument/SF/forskrift/2000-12-01-1208?q=FOR-2000-12-01-1208>

[Last accessed on December 15, 2015]



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Regulation on Priority Setting FOR-2015-04-10-339

<https://lovdata.no/dokument/SF/forskrift/2000-12-01-1208?q=FOR-2000-12-01-1208>

[Last accessed on December 15, 2015]

Ringard, Å., B. I. Larsen, O. F. Norheim (2012), ‘Medisinsk metodevurdering (HTA) for bedre prioriteringer av helsetjenester’ [Health technology assessment for better priority setting in the health care services], *Michael*, 9: 174-182.

Ringard, Å., B. Mørland and B. I. Larsen (2012), ‘Quality and priorities in the health services’, *Journal of the Norwegian Medical Association*, 3: 312-4.

Ringard, Å., B. Mørland and J-A. Røttingen (2010), ‘Åpne prosesser for prioritering’ [Open process for priority setting], *Journal of the Norwegian Medical Association*, 130: 2264-2266.

Robberstad, B. (2015), ‘Age and severity’, *Journal of the Norwegian Medical Association*, 135: 1376-1378.

Rumbold, B. E., A. Weale, A. Rid, J. Wilson and P. Littlejohns (forthcoming), ‘Public reasoning and health care priority setting: The case of NICE’, *Kennedy Institute of Ethics Journal*.

---

Wang, H. and C. Høymork (2014), 'Er alle gode ting tre?' [Are three criteria sufficient for priority setting?], *Journal of the Norwegian Medical Association*, 134: 1260-1262

Website for the Norwegian National Council for Priority Setting in Health Care:

<http://www.kvalitetogprioritering.no/hjem> [Last accessed on December 15, 2015]

Wisløff, T. (2015), 'Priority-setting criteria in the Norwegian health services', *Journal of the Norwegian Medical Association*, 135: 1373-1375.

## Tables

Table 1. The three official priority-setting criteria

The three official priority-setting criteria:	
<i>Severity of health state</i>	as determined by prognosis for loss of life, diminished physical or mental functioning, and pain
<i>Expected benefit of treatment</i>	as determined by increased probability of survival, improved physical or mental functioning, and reduced pain
<i>Cost-effectiveness of treatment</i>	the costs should stand in a reasonable relation to the benefits of the treatment
(NOU, 1997; Norheim, 2003)	

The criteria are to be applied together, such that a treatment must meet all three criteria in order to be given priority. The criteria were intended as overarching criteria for priority-setting at all levels of the health care services (Directorate of Health, 2012; NOU 1997), and are reflected both in legislation and in practice in various ways. Importantly, until 2015, the criteria were codified in the Patient Rights Act (LOV-1999-07-02-63) and its section 2.1b, Regulation on Priority Setting (FOR-2000-12-01-1208). This law grants patients a right to health care, provided that the health condition is severe and that the costs of treatment are ‘reasonable’ relative to the expected benefit. The criteria are also embedded in the Regulation on Medicines (FOR-2010-06-23-957), which governs the evaluation of new drugs for inclusion in the prescription reimbursement scheme (NOU, 2014; Wisløff, 2015).

Table 2. The Council’s case procedure

<i>Case submission</i>	As of 2011, the Council operates with an open submission policy whereby anyone, including the public, can propose a case. Prior to this policy, case proposals could only be submitted by the Department of Health, Council members and the Secretariat.
<i>Preliminary assessment and selection of cases</i>	The Secretariat reviews submitted proposals. In principle, the Secretariat may refuse proposals that are deemed not relevant for the Council’s work. But granted that a case meets this minimum requirement, the Secretariat will conduct a preliminary assessment of the case, together with the proposer, intended to give a broad overview of relevant information and

<p><i>Comprehensive assessment and case presentation</i></p>	<p>highlight key issues. This assessment, presented in a case vignette, informs the Council's decision about whether to proceed with the case.</p> <p>If the Council accepts a case, the Secretariat and the proposer will proceed to conduct a more thorough assessment. This assessment covers a wide range of available information, including systematic reviews and health technology assessments conducted by the Norwegian Knowledge Centre for the Health Services, as well as other kinds of evaluations delivered by other independent research organisations. The Secretariat will also typically identify and provide background information on other aspects of the case, such as whether a treatment's compliance with the official priority-setting criteria has been evaluated, various ethical issues, the patient perspective, and the Council's or other parties' previous treatment of similar cases. The Secretariat will consult a wide range of sources, including resource and knowledge centres, health care professionals and specialists, user and patient organisations, ethicists, and health management. The assessment is summarised in a case presentation document, which is distributed to members of the Council, along with the reports and evaluations on which it is based.</p> <p><i>Deliberation and decision</i></p> <p>The Council members will discuss the case and reach a decision in the course of one or more Council</p>
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meetings. Meetings will also typically involve presentations by experts in the field and occasionally representatives from user and patient organisations. The Council is explicit in endorsing a consensus-based approach. If a consensus cannot be obtained, members will vote in order to make a final decision.

(The Council website)

Table 3. Case summaries and decisions

Case	Year	Central question	Recommendation	Justification		Other justificatory reasons
				Official priority-setting criteria		
				Direct	Indirect	
Cochlear implants	2007	Should a second implant for adults qualify as 'necessary health care' under the Patient Rights Act?	As a general rule, patients should have a right to one but not two cochlear implants. A second implant may be granted subject to individual assessment, ('on the basis of the Regulation on Priority Setting').	Many individuals could benefit from a second implant, but the costs are too high relative to the benefit to grant a right.		
Heart valves	2008	Should catheter-based implantation of heart	Catheter-based implantation of heart valves should not be	On the basis of available evidence, the treatment is		

HPV vaccine	2008	Should the HPV vaccine be included in the children's national vaccination programme?	valves be offered in Norway?  The HPV vaccine should be offered as part of the children's national vaccination programme.	offered to patients in Norway at this time.  There is reasonable certainty that the vaccine is effective. The costs are high, but not sufficiently so to count against inclusion of the vaccine.	considered experimental.  The Council emphasises that the intervention is preventive. The Council emphasises that including the vaccine in the national programme could help reduce social inequalities in health.
Left ventricular assist device	2008	Should a left ventricular assist device (mechanical heart pump) be offered to patients, either as a temporary solution or as a permanent solution (instead of transplant)? Patients with severe final stage heart failure.	The heart pump should only be offered as a temporary solution for patients awaiting a transplant. It should not replace heart transplants as the preferred long-term treatment for this patient group.	This patient group has a very poor prognosis. The clinical effectiveness of the treatment is not sufficiently documented, and it is considered investigational. The costs are considerable, but it is currently not possible to establish whether they are reasonable compared to the benefits.	
Monoclonal antibodies	2008	Should monoclonal antibodies be included in the standard treatment of metastatic colorectal cancer?	The medication should be offered to patients as part of a clinical phase IV trial.	Metastatic colorectal cancer is a severe disease with high mortality. The costs of the treatment are high.	Monoclonal antibodies are already in use as first and third line treatment. The decision does not involve an increase in general health care expenditure.
Newborn screening	2008	Should the current programme be expanded to include screening for an additional	The Council supports the recommendation of the Directorate of Health initiated work group to expand		The work group concluded that screening for these conditions complied with the WHO

Genetic testing	2009	21 rare congenital metabolic disorders? Should all women with recently diagnosed breast or ovary cancer be offered genetic testing, even in the absence of a family history of cancer?	the screening programme.  Genetic testing should only be offered subject to risk assessment, in particular family history of cancer.	There was disagreement on whether the effectiveness of testing of women without a family history of cancer was sufficiently well documented.	There was uncertainty regarding how many false positives would result in mastectomy or hysterectomy.	criteria for screening. <sup>10</sup>
Breast reconstruction surgery	2010	Should consideration for reconstructive breast surgery by individual assessment be included in the treatment plans for breast cancer?	Consideration for reconstructive surgery should be part of the treatment options offered to breast cancer patients.			The Council makes their recommendation 'on the basis of international guidelines'.
Screening for colorectal cancer	2010	Should Norway establish a national screening programme for colorectal cancer?	The Council recommends a 'cautious approach'. In the first instance, screening for colorectal cancer should only be offered to selected groups as part of a pilot study.	Colorectal cancer is a major public health issue with high morbidity and mortality. Screening is the only intervention known to reduce morbidity and mortality.	Further examinations subsequent to positive testing may give rise to complications.	Screening could give rise to fear in the population.
Early ultrasound	2011	Should early ultrasound scans (week 11-13) be included as part of routine antenatal examinations?	Routine ultrasound should be offered in weeks 11-13 and 17-19.			
Smoking cessation	2011	Should smoking cessation aids be offered by the health care services? What can be	The municipal health care services and the GPs should improve and systematise the smoking	Smoking cessation aids are effective and cost-effective.		



		done to improve the quality and scope of smoking cessation assistance offered via the health care services?	cessation aids that they offer. The Regulation on Medicines should be modified to enable free prescription of smoking cessation medication.		
Rotavirus vaccine	2012	Should the rotavirus vaccine be included in the national children's vaccination programme?	The vaccine should not be included in the national vaccination programme.	Rotavirus infection is not considered a severe disease.	To ensure the public's support of the vaccination programme, the public must have faith in the necessity of vaccination for the prevention of severe disease.
Climate therapy abroad	2013	Should the climate therapy abroad scheme for patients with chronic disease be continued? Should this scheme be extended to more patients?	The scheme should be continued in its current form. Which groups should be eligible for the scheme needs to be reconsidered.		
Left ventricular assist device	2013	Should a left ventricular assist device (mechanical heart pump) be offered to patients as a permanent solution?	The heart pump should be offered as a permanent solution to carefully selected patients who do not meet the eligibility criteria for a heart transplant.	The heart pump could enhance survival and improve quality of life for carefully selected patients. [] The Council expects reduced costs and improved clinical effectiveness with time.	
Screening for cervical cancer	2013	Should the method for screening for cervical	The HPV test should be piloted in the Norwegian		

Screening for postnatal depression	2013	cancer be changed, by testing for HPV virus infection in addition to the standard smear test? Should screening for postnatal depression with the Edinburgh Postnatal Depression Scale (EPDS) be routinely offered in Norway?	health care services. Screening for postnatal depression should not be routinely offered at this time.	Screening with the EPDS does not meet the WHO criteria for screening.
Long-term mechanical ventilation	2014	Does long-term mechanical ventilation for patients with amyotrophic lateral sclerosis meet the priority-setting criteria?	Long-term mechanical ventilation does not meet the priority-setting criteria. This treatment option should only be offered to especially motivated patients and after thorough assessment.	Long-term mechanical ventilation does not meet the priority-setting criteria.
Surgical treatment of obesity	2014	Should action be taken to curb the increase in surgical treatment of obesity?	Non-surgical interventions against obesity should be given higher priority. The Council recommends against restricting eligibility for surgery at this time.	Obesity is a severe condition. Surgical treatment results in significant and rapid weight loss. Long term effects on morbidity and quality of life are not well known. Risks of complications and side effects are substantial. Surgery commonly requires lifelong follow up by the health care services.

The wording of the recommendations and justifications has been kept as close as possible to the Council's own, but are not direct citations unless otherwise indicated. The central question is reconstructed on the basis of case vignettes, meeting minutes and the final decision.

Table 4. Summary of the Council's use of the official priority-setting criteria

Case	Recommendation	Use of priority criteria	
		Criterion	Is the criterion met
Cochlear implants	Mixed	Expected benefit Cost-effectiveness	Yes No
Heart valves	Rejection	Expected benefit	No
HPV vaccine	Approval	Expected benefit Cost-effectiveness	Yes Yes
Left ventricular assist device (2008)	Rejection	Severity Expected benefit Cost-effectiveness	Yes No No
Monoclonal antibodies	Treatment available to selected patients as part of research	Severity Cost-effectiveness	Yes ?
Newborn screening	Approval		
Genetic testing	Rejection	Expected benefit	?
Breast reconstruction surgery	Approval		
Screening for colorectal cancer	Treatment available to selected patients as part of research	Severity Expected benefit	Yes ?
Early ultrasound	Approval		
Smoking cessation	Approval	Expected benefit Cost-effectiveness	Yes Yes
Rotavirus vaccine	Rejection	Severity	No
Climate therapy abroad	Approval		
Left ventricular assist device (2013)	Approval	Expected benefit Cost-effectiveness	Yes ?

Screening for cervical cancer	Treatment available to selected patients as part of research		
Screening for postnatal depression	Rejection		
Long-term mechanical ventilation	Mixed	Cost-effectiveness	No
Surgical treatment of obesity	Mixed	Severity Expected benefit	Yes ?

? : It is unclear what the Council concluded regarding whether the criterion was met.